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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/622,487

08/17/00

SUMIDA

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0263-4047

HM22/0824

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EXAMINER

MOEZIE, F

ART UNIT

PAPER NUMBER

1653

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/622,487

Applicant(s)  
SUMIDA

Examiner  
F. MOEZIE

Art Unit  
1653



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☒ Responsive to communication(s) filed on 3/5/99 and 8/17/00

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1-12 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some\* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_

3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3

20) ☐ Other:

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## **DETAILED ACTION**

### **STATUS OF CLAIMS**

Claims 1-12 are pending examination in this Office action.

### **REJECTION - 35 U.S.C. 112, FIRST AND SECOND PARAGRAPHS**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polysorbate 20 and possibly polysorbate 80, does not reasonably provide enablement for the numerous structurally different surfactants set forth in claim 7, specially the cationic and neutral surfactants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factor to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Foreman*, 230 USPQ 546 (Bd Apls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,

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- 2) the amount of direction and guidance provided,
- 3) The presence or absence of working examples,
- 4) The nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breath of the claims.

Applicant fails to set forth the criteria for "a stable G-CSF formulation". Additionally, applicant fails to provide information allowing the skilled artisan to know the molar amounts for the surfactants of varying size and properties that gives rise to the stability for the G-CSF. The molecular weight for the G-CSF is constant throughout, however the same is not true for the various surfactants cited in claim 7. In the case of cationic surfactants, additionally, the environment for the stable formulations differs drastically from a neutral or non-ionic surfactant. A protein such as G-CSF having a MW of about 20,000 d may not be stable under the conditions and/or environments as claimed. Further, applicant fails to cite the length of time that the claimed stability remains in effect, i.e., the "unique property" for the claimed formulations. The instant claims read on a mixture of components and the determination of a "surfactant" that would results in "a stable" formulation for any length of time, necessitates an exhaustive search. Hence, it would be an undue burden to practice the invention.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Regarding claims 1-12, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

The terms "at least", "less" (claim 1); "substantially" (claim 6) are a relative terms which render the claim indefinite as to the claims' metes and bounds.

Claims 4 and 5 are duplicative of one another.

Claim 12 is duplicative of claim 1, being drawn to the same formulation.

**REJECTION -35 U.S.C. 102 (a or b)/103 (a) and 35 U.S.C. 103 (a)**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 are rejected under 35 U.S.C. 102(a or b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Michaelis et al. in US 5,919,443 (effective filing date 6/15/95) or US 5,919,757 (filed 5/15/97).

The '443 document teaches a stable preparation comprising G-CSF and an amount of surfactant which is no greater than the amount of G-CSF (claim 14). The pH of the preparation is about 7 or lower (Table 5 and 9, for example), wherein the use of low amounts of surfactant is taught (col. 3, lines 51-52). See, the entire document, especially Tables 2, 4, 6, 9 and claims 14 and 24.

The '757 document teaches an aqueous preparation with a long shelf life comprising G-CSF and at least one surfactant (Abstract) such as polysorbate 80. The formulation is kept at pH

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of less than 7.0 (4.5-6.5 - Table 5a). See the entire document, especially Tables 4a and 5a and claims 1 and 3.

The claims being drawn to a stable formulation comprising G-CSF and a surfactant at pH of 7.0 or less, as taught by Michaelis, are anticipated and/or rendered obvious in view of the art.

Claims 1-12 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Michaelis '443 and '757 (above) and Woog et al in US 5,503,827 (effective filing date 2/15/95).

The teachings of the first two references have been disclosed above. Woog document teaches a composition comprising G-CSF and polysorbate 80 at pH of about 4.5, wherein no additional protein is used (Example 5). See the entire document, especially col. 5, lines 30-33 wherein the choice of pH values in the formulation is dependent upon the use for the formulation.

An ordinary art skilled at the time the invention was made would have been motivated to vary the conditions (pHs or amounts of ingredients in the formulation) depending on the use for the formulation - absent unobvious findings.

Any inquiry concerning this communication should be directed to F.T. Moezie at telephone number (703) 305-4508 or Dr. LOW (SPE) at 308-2923.

*F. T. Moezie*  
F. T. MOEZIE, PH.D.  
PRIMARY EXAMINER  
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